

**WHAT IS CLAIMED IS:**

1. A biological fluid constituent sampling and analyte concentration measurement device comprising:
  - (a) an elongated member having an open distal end configured to pierce a skin surface and to provide access to the biological fluid;
  - (b) concentrically-spaced electrodes positioned within the elongated member that define an electrochemical cell for measuring the concentration of a target analyte within the biological fluid; and
  - (c) a constituent transfer medium comprising a hydrophilic material in fluid communication with the elongated member and with the electrochemical, wherein the constituent transfer medium transfers at least one biological fluid constituent present at the open distal end of the elongated member into the electrochemical cell.
2. The device of claim 1 wherein the electrodes define a reaction zone and wherein the hydrophilic material occupies the reaction zone.
3. The device of claim 2 further comprising a redox reagent system in contact with the reaction zone.
4. The device of claim 1 further comprising a signal producing and receiving means in electrical communication with the electrodes.
5. The device of claim 1 wherein the elongated member comprises a lumen, wherein the open distal end provides a passageway into the lumen.
6. The device of claim 5 wherein the lumen is substantially filled with the hydrophilic material.

7. The device of claim 1 wherein the hydrophilic material comprises a gel matrix.
8. The device of claim 1 wherein the biological fluid is interstitial fluid and the analyte is glucose.
9. A device for sampling biological fluid constituents and measuring the concentration of at least one target constituent in the biological fluid, comprising:
  - a first electrode having a first length;
  - a second electrode having a second length greater than the first length and concentrically positioned about and spaced apart from the first electrode, wherein the second electrode is configured for piercing the skin; and
  - a hydrogel material within the space between the first and second electrodes.
10. The device according to claim 9 having a penetration length no deeper than the dermis.
11. The device according to claim 10 having a penetration length no deeper than the epidermis.
12. The device according to claim 9 wherein the second electrode has an open distal end and defines a space within the device and wherein the space is substantially filled with the hydrogel material.
14. The device according to claim 9 further comprising a reagent in contact with at least one of the electrodes or the hydrogel material within the space between the first and second electrodes.
15. The device according to claim 14 wherein the reagent is located on a surface of at least one of the electrodes in contact with the hydrogel material.

16. A micro-needle for sampling a biological fluid constituents and measuring a target constituent within the biological fluid, comprising:

- a core having a length;
- a first electrode coaxially conformed about the core length;
- a second electrode coaxially spaced-apart from the first electrode and having a length that extends beyond the core length and terminates at an open tip; and
- a hydrogel material located between the first and second electrodes; and
- a reagent contained within the micro-needle wherein the reagent is selected based on the target constituent.

17. The micro-needle according to claim 16 further comprises a plating formed circumferentially about the length of the second electrode.

18. A biological fluid constituent sampling and analyte concentration measurement device, said device comprising:

- (a) an elongated hollow member having an open distal end configured to pierce a skin surface and to provide access to the biological fluid and a proximal end;
- (b) two parallelly-spaced electrodes positioned at the proximal end of the elongated hollow sampling means that define an electrochemical cell for measuring the concentration of analyte within the biological fluid; and
- (c) a constituent transfer medium comprising a water-absorbent material in fluid communication with the elongated hollow member and with the electrochemical cell, wherein the constituent transfer medium transfers biological fluid present at the open distal end of the at least one piercing member into the electrochemical cell.

19. The device of claim 18 wherein the electrodes define a reaction zone and wherein the water-absorbent material occupies the reaction zone.

20. The device of claim 19 further comprising a redox reagent system in contact with the reaction zone.

21. The device of claim 18 further comprising a signal producing and receiving means in electrical communication with the electrodes.

22. The device of claim 18 wherein the elongated hollow member is substantially filled with the water-absorbent material.

23. The device of claim 18 wherein the water-absorbent material comprises a gel matrix.

24. The device of claim 18 wherein the biological fluid is interstitial fluid and the target analyte is glucose.

25. The device of claim 18 wherein a first electrode radially extends from the proximal end of the elongated hollow member.

26. The device of claim 25 wherein the first electrode has an annular configuration.

27. The device of claim 26 wherein a second electrode has a circular disk configuration.

28. A system for sampling biological fluid constituents from the skin of a patient and measuring a target constituent within the biological fluid, the system comprising:

(a) at least one micro-needle at least a portion of which is hollow and having an open distal end for accessing the biological fluid;

- (b) an electrochemical cell associated with the micro-needle, the cell comprising a reference electrode and a working electrode spaced apart from each other;
- (c) a water-absorbent gel matrix at least partially contained within the hollow portion of the micro-needle and the space between the electrodes; and
- (d) a control unit in electrical communication with the electrochemical cell, comprising:
  - (1) means for sending an electrical reference signal to the reference electrode and for receiving an electrical output signal from the working electrode, and
  - (2) a software algorithm which automatically calculates and determines the concentration of the target constituent in the biological fluid upon receipt of the electrical output signal.

29. The system according to claim 28 further comprising a display unit in electrical communication with the control unit for displaying information in the form of electrical signals received from the control unit related to the sampling and the measuring of the target constituent.

30. The system according to claim 28 further comprising a housing and a support means wherein the control unit is housed within the housing and the at least one micro-needle is mounted to the support means.

31. The system of claim 28 wherein the gel matrix comprises a natural gel.

32. The system of claim 31 wherein the natural gel is selected from the group comprising agarose, gelatin, mucopolysaccharide, starch and the like.

33. The system of claim 28 wherein the gel matrix comprises a synthetic gel.

34. The system of claim 33 wherein the synthetic gel comprises a neutral water-soluble polymer.

35. The system of claim 28 wherein the reference and working electrodes each have a cylindrical configuration and are spaced from each other in a co-axially relationship.

36. The system of claim 28 wherein the electrochemical cell is at least partially housed within the micro-needle.

37. The system of claim 28 wherein the reference and working electrodes each have a planar configuration and are spaced from each other in a parallel relationship.

38. The system of claim 28 wherein the electrochemical cell is adjacent to a proximal end of the micro-needle.

39. The system of claim 28 comprising an array of micro-needles.

40. A method for determining the concentration of at least one target constituent contained within biological fluid, the method comprising the steps of:  
providing at least one micro-needle comprising an open distal end and a lumen;  
providing an electrochemical cell within the lumen, the electrochemical cell comprising a concentrically-layered electrode configuration;  
inserting the open distal end of the micro-needle into the skin to a selected depth;  
transferring a sample of at least one target constituent within the biological fluid present at the open distal end through the lumen and into the electrochemical cell;  
providing a first electrical signal to the electrochemical cell; and  
receiving a second electrical signal generated by the electrochemical cell, wherein the second electrical signal is representative of the concentration the constituent in the biological fluid.

42. A method for determining the concentration of at least one target constituent contained within biological fluid, the method comprising the steps of:

- providing at least one hollow micro-needle comprising an open distal end, an open proximal end and a lumen extending there between;
- providing an electrochemical cell in fluid communication with the hollow micro-needle, the cell comprising a parallelly-spaced electrode configuration, wherein the electrode configuration is positioned at the open proximal end of the hollow micro-needle substantially transverse to the micro-needle;
- inserting the open distal end of the hollow micro-needle into the skin to a selected depth;
- transferring a sample of the at least one targeted biological fluid constituent present at the open distal end of the hollow micro-needle into the electrochemical cell;
- providing a first electrical signal to the electrochemical cell; and
- receiving a second electrical signal generated by the electrochemical cell, wherein the second electrical signal is representative of the concentration the constituent in the biological fluid.

43. A method according to claim 40 or 41 wherein the selected depth is no greater than the viable epidermis.

44. The method according to claim 43 wherein the selected depth is no greater than the stratum corneum.

45. A method according to claim 40 or 41 wherein the step of transferring comprises providing a hydrophilic gel material within the micro-needle lumen and in contact with the electrochemical cell, wherein the hydrophilic gel material absorbs at least one target constituent within biological fluid present at the open distal end of the micro-needle.

46. A method according to claim 40 or 41 wherein the steps of providing a first electrical signal and receiving a second electrical signal is performed by a control unit in electrical communication with the electrochemical cell.

47. A method according to claim 40 or 41 further comprising the step of deriving the concentration of the constituent in the patient's biological fluid from the second electrical signal.

48. The method according to claim 47 further comprising the step of displaying a numerical value representative of the concentration of the constituent in the patient's biological fluid.

49. The method according to claim 47 wherein the step of deriving comprises using a software algorithm.

50. The method of claim 45 further comprising the step of allowing the concentration of the at least one targeted constituent in the hydrophilic gel material to equilibrate with the concentration of the at least one targeted constituent within biological fluid in the patient's skin prior to the step of providing a first electrical signal to the electrochemical cell.

51. The method of claim 45 wherein the step of providing a first electrical signal to the electrochemical cell is performed prior to the time it takes for the concentration of the at least one targeted constituent in the hydrophilic gel material to equilibrate with the concentration of the least one targeted constituent within biological fluid in the patient's skin.

52. A kit comprising at least one biological fluid constituent sampling and concentration measurement device according to claim.



53. The kit of claim 52 further comprising a means for controlling the at least one biological fluid constituent sampling and analyte concentration measurement device.

54. A kit for sampling a biological fluid constituent from the skin of a patient and for measuring the concentration of a constituent within the sampled biological fluid, the kit comprising:

at least one micro-needle according to claim 16.

55. The kit according to claim 54 further comprising a plurality of micro-needles and a support member wherein the plurality of micro-needles are arranged in an array on the support member.

56. The kit according to claim 55 wherein the micro-needles have varying lengths.

57. The kit according to claim 55 further comprising one or more reagents for facilitating the measurement of one or more targeted constituents within the sampled biological fluid.